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Modeling an IT Support for Handling Serious Adverse Events in Clinical Trials

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Abstract

Serious adverse events (AE) or reactions (AR) may occur in clinical trials and require particularly regulated reporting. Manual management is inefficient and ineffective. Based on a description of regulations, we have developed a data model with class-, state-, use-case- and activity diagrams, which can be used for automatic code generation of an assisting software tool for AE / AR data management.

Keywords:

Clinical Trial, Adverse Event, Software Engineering

Introduction

Several IT systems are used to support clinical trial conduction but they are usually disconnected from the hospital information systems (HIS). Therefore, the principle investigator of a controlled clinical trial might not be informed when a serious adverse event (SAE) or a suspected unexpected serious adverse reaction (SUSAR) occur. To ensure information exchange between the HIS and the clinical trial management system (CTMS), we model an appropriate IT infrastructure supporting SAE / SUSAR identification. Furthermore, the tool is designed to support and assist the trial team in timely and accurate reporting of such events.

Methods

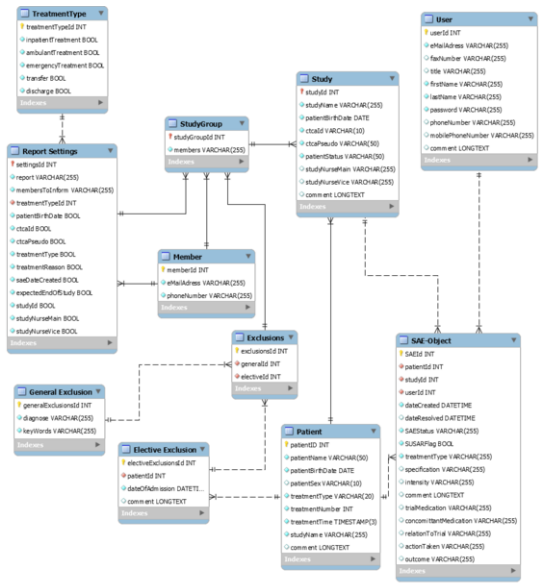
There are several software engineering tools, such as the unified modeling language (UML) [1] used to describe the functional requirements for the SAE tool and the occurring processes within models provided by the UML. Based on a comprehensive description of regulatory requirements and a desired workflow [2], we created

- Use-case diagrams to describe functionalities from the user's view;
- Activity diagrams to represent the data- and controlflow;
- Class diagrams to define the structure of the system;
- State diagrams to compose a finite number of system states.

These models serve as basis for the automated code generation [3] of an web-based SAE management tool, its documentation, and the verification of the implemented source code.

Results

The SAE management is divided into two processes: automatic SAE identification and manual monitoring of SAEs including parallel automatic support. In a relational data model, only eleven tables are required.



Discussion

Comprehensive modeling supports the developer during the implementation process. The software will simplify the management of SAEs in clinical trials. Automatically generated messages guide research nurses to keep track of SAEs, lower the risk of missing a case, and increase security and quality of clinical trials in general.

References

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